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	•		1654			
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

		Application No.	Applicant(s)
		10/564,788	HUMMEL ET AL.
	Office Action Summary	Examiner	Art Unit
		Ronald T. Niebauer	1654
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE in a soint of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. In period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from to cause the application to become ABANDONE	I.  lely filed  the mailing date of this communication.  O (35 U.S.C. § 133).
Status			
2a)□	Responsive to communication(s) filed on <u>27 Au</u> This action is <b>FINAL</b> . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro	
Dispositi	on of Claims		
5)□ 6)⊠ 7)□	Claim(s) <u>62-124</u> is/are pending in the application 4a) Of the above claim(s) <u>62-84 and 86-123</u> is/a Claim(s) <u>is/are allowed.</u> Claim(s) <u>85 and 124</u> is/are rejected. Claim(s) <u>is/are objected to.</u> Claim(s) <u>are subject to restriction and/or and/or claim(s) <u>are subject to restriction and/or claim(s) <u>are subject to restriction and/or claim(s)</u></u></u>	are withdrawn from consideration	•
Applicati	on Papers		
10)⊠	The specification is objected to by the Examiner The drawing(s) filed on 17 January 2006 is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction to the oath or declaration is objected to by the Examiner.	a) ☐ accepted or b) ☒ objected drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).
Priority u	ınder 35 U.S.C. § 119		
a)[	Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the priority application from the International Bureau  See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachman	Ne)	•	
2) 🔲 Notic 3) 🔯 Inforr	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>1/17/06</u> .	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa	te

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#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election with traverse of Group II claims 85-101 and the species of compound number 352 of new claim 124 and the species of chemical bond in the reply filed on 8/27/07 is acknowledged. The traversal is on the ground(s) that the reference will be antedated by a perfection of the foreign priority and that the reference teach away from the current invention as the compounds are not C5a receptor antagonists in a narrow sense. This is not found persuasive because an English translation of the EP application has not been received. Further, the claims recite that the compound is 'preferably a C5a receptor antagonist' so there is no requirement that the compounds be antagonists even in a narrow sense. Further, Kawai et al. (cited below) teach the compound (N-Methyl)Phenylalanyl-Lysyl-Prolyl-{(2R)-2-amino-3-cyclohexylpropanoyl}-Phenylalanyl-D-(N-Methyl)-Phenylalanyl-OH (example 171 (column 52)) which meets the limitations of claim 85 as discussed below, therefore the claimed invention makes no contribution over the prior art

The requirement is still deemed proper and is therefore made FINAL.

The procedure for examination of Markush type claims is highlighted in MPEP section 803.02:

Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

The examination will be extended to the extent necessary to determine patentability

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of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action can be made final unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

In the instant case, the elected species was examined and prior art was found that rendered the species obvious. Since art was found on a species in the genus, the examination has been extended to the extent necessary to determine patentability of the Markush-type claim. The Markush-type claim is rejected and claims to nonelected species held withdrawn from further consideration. It is noted that in the course of searching for the elected species, art was found that reads on non-elected species and is cited herein.

Claims 62-84,86-123 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/27/07.

New claims 123-124 have been added. It is noted that new claim 123 depends from claim 62 which was part of Group I of the restriction requirement. Hence claim 123 is withdrawn as being drawn to a non-elected invention.

Claims 1-61 were previously cancelled. Claims 85,124 are under consideration.

#### **Priority**

Receipt is acknowledged of papers (certified copy of foreign document) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that a

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translation of the foreign document has not been provided. Further, support in the foreign document for the elected species should be identified.

#### Claim Objections

Claim 124 is objected to because of the following informalities: Claim 124 does not end in a period. MPEP § 804.01(m) states that, "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995)."

Appropriate correction is required.

### **Drawings**

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figure 1 and Figure 2 as described on page 72 of the specification are not labeled in the actual drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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### Specification

The disclosure is objected to because of the following informalities: the description of the drawings (page 72) should include a heading 'Brief description of the drawings' (see 37 CFR 1.77 (b) 8 and 37 CFR 1.77 (c)).

Appropriate correction is required.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 85 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 85 recites mimics, analogs, and derivatives. The specification page 67 defines derivatives and analogues very broadly. The specification pages 68-69 defines mimics very broadly. From the definitions provided one of ordinary skill in the art would not recognize what actually falls within the definition of mimic, derivative or analogue. In particular, since the definition of mimic is coupled to a functional property, what exactly could be classified as a mimic is unclear. The specification does not convey to one of ordinary skill in the art what modifications and/or changes are permissible to a compound of formula II to render it a mimic, analog, or derivative. Further, it is unclear how a mimic differs from an analog or a

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derivative and vice versa. The definitions provided do not clearly define the meets and bounds of the claimed invention.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the mainer and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 85 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co. the court stated:

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"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Fiers, 984 F.2d at 1171, 25 USPQ2d 1601; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and

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would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a prima facie case are discussed below.

In the instant case, claim 85 is drawn to a compound of general formula II.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

Formula II X1-X2-X3-X4-X5-X6-X7-X8 includes position X2,X5,X6,X7 which are radicals that are mimics. X3, X4, and X7 can be amino acid analogs or derivatives. The specification page 67 defines derivatives and analogues very broadly. The specification pages 68-69 defines mimics very broadly. In considering the possible variability, if only 50 different mimics/analogs/derivatives are considered (there are many more possible mimics/analogs/derivatives) at X2-X8 there would be 7<sup>50</sup> possible compounds. Hence, there is substantial variability in the genus.

Approximately 400 different compounds are shown in the specification, for example on pages 48-52. However the compounds do not even represent a billionth of the compounds possible (using the conservative estimate of 7<sup>50</sup> possible compounds recited above). One of skill in the art would not conclude that applicant was in possession of all possible compounds.

Since there are a substantial variety of compounds possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claim 85 recite that the radical mimic the biological binding characteristics of particular amino acids. However, there is no disclosure of a correlation between this functional property and the structure of the polypeptides. In particular, no common sequence or common core is taught for the analogs or derivatives.

(5) Method of making the claimed invention:

The specification (such as example 1) describes synthesis of compounds, however the specification fail to describe the synthesis of a representative number of compounds.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 85 is/are broad and generic, with respect to all possible analogs/mimics encompassed by the claims. The possible structural variations are limitless to any analog/derivative. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the polypeptides beyond those polypeptides specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of polypeptides identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the

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specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 85 is rejected under 35 U.S.C. 102(b) as being anticipated by Kawai et al. (US 5,387,671).

Kawai teach C5a receptor modulating compounds where the groups are connected via chemical bonds (claim 1 and column 1-2). Kawai specifically teach the compound (N-Methyl)Phenylalanyl-Lysyl-Prolyl-{(2R)-2-amino-3-cyclohexylpropanoyl]-Phenylalanyl-D-(N-Methyl)-Phenylalanyl-OH (example 171 (column 52)). See also a related compound in the discussion of the prior art on page 4 last paragraph of the specification of the current invention. In comparing the compound of Kawai to the compound of the current invention X1 is N-methyl (i.e. alkyl), X2 is Phe, X3 is Lys, X4 is Pro, X5 is (2R)-2-amino-3-cyclohexylpropanoyl (a mimic of cyclohexylalanine), X6 is Phe (a mimic of Trp), X7 is N-methylPhe (a mimic of Phe),

X8 is OH. Therefore the compound of Kawai meets the limitations of claim 85 of the current invention.

Regarding claim limitations, the recitation 'preferably a C5a antagonist' does not require a particular structure and does not limit the claim to a particular structure. The radicals taught by Kawai at positions X2, X5, X6, X7 meet the limitations of being a mimic as broadly defined in the application (page 68-69 of specification). For example, Phe at position 6 is a mimic of Trp because both can establish hydrophobic interactions.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 85,124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al. (as cited above).

As discussed above Kawai teach C5a receptor modulating compounds (claim 1 and column 1-2). Kawai specifically teach the compound (N-Methyl)Phenylalanyl-Lysyl-Prolyl-{(2R)-2-amino-3-cyclohexylpropanoyl]-Phenylalanyl-D-(N-Methyl)-Phenylalanyl-OH (example 171 (column 52)) which anticipates and renders obvious claim 85.

Kawai does not teach an embodiment or specific example of the elected species.

In claim 1, Kawai teach a broad genus of compounds of the formula A-B-D-E-G-J-L-M-Q (shown schematically in columns 9-12). Many compounds, including the elected species Hoo-

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Phe-Orn-Pro-hle-Pff-Phe-NH2 (compound 352 of claim 124) are rendered obvious from the genus taught by Kawai. In comparing the current invention to that of Kawai a comparison will be made between each of the radicals X1-X8 as defined in claim 85 of the current invention. Instead of identifying each of R1-R300+ of Kawai, the examples of Kawai will be used to illustrate the genus of compounds.

From example 171 of Kawai discussed above, X2 is Phe, X4 is Pro, X7 is Phe. Hence the corresponding residues of the elected species are clearly within the genus taught by Kawai. Further, Kawai teach example 74 with Orn at X3, and example 5 with leucine at position X5 (if Leu is a member of the genus then Hle is clearly within the genus as well). Kawai teach that the terminal radical (R25-R26-R27 of claim 1) can be NR109 with R109 being hydrogen, R26 being absent and R27 being hydrogen resulting in X8 of the current invention. Since aryl (R1) is defined to be substituted or unsubstituted aromatic, Hoo (substituted pyrimidine) is possible at X1 and fluorenyl is possible at position X6.

#### In summary:

Elected species	Ноо-	Phe-	Orn-	Pro-	hle-	Pff-	Phe	-NH2	
Kawai example 171	xxx	Phe	xxx	Pro	xxx	Phe	m-Phe	;	
Kawai example 74	xxx	Phe	m-Orn	Pro	xxx	xxx	xxx		
Kawaii example 5	xxx	Phe	xxx	xxx	Leu	xxx	xxx		
Kawai claim 1	A	В	C	D	G	J .	L	M	Q (where for
example, B and D together can represent a particular group).									

Taken together the elected species falls within the genus of claim 1 of Kawai. Therefore the elected species is a species of the genus described in Kawai.

It has been recently held that "Neither §103's enactment nor *Graham*'s analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art." <u>KSR v. Teleflex</u>, 550 U.S. \_\_\_\_\_, 82 USPQ2d 1385, 1389 (2007). The KSR court stated that "a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR at 1389. The Supreme Court stated that there are "[t]here cases decided after Graham [that] illustrate this doctrine." <u>KSR</u> at 1395. "In <u>United States v. Adams</u>, 383 U.S. 39, 40, 148 USPQ 479 (1966) ... [t]he Court recognized that when a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." <u>KSR</u> at 1395. Thus, the mere substitution of one known element for another to obtain a predictable result is obvious.

Furthermore, The KSR court concluded that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR

When there is motivation

"to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, \_\_\_\_, 82 USPQ2d 1385, 1397 (2007).

In the instant case, one would be motivated to derive the compounds discussed in Kawai (see claim 1), particularly compounds with Phe or Phe derivatives at the C-terminal end based on example 170 and 171 of Kawai (column 52). From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. In the instant case, there are a finite number of possible

compounds described by Kawai. The claim would have been obvious because a person of ordinary skill would have good reason to pursue the known options within his or her technical grasp.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

#### Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPO 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 85,124 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 24,44 of copending Application No. 11814050. This is a <u>provisional</u> double patenting rejection since the conflicting claims have not in fact been patented.

Claim 24 of copending Application No. 11814050 is identical to claim 85 of the current application. Claim 44 of copending Application No. 11814050 recites identical species as claim 124 of the current application such as the elected species. Hoo-Phe-Orn-hle-Pff-Phe-NH2 (compound 352).

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059.

The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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